U S ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington DC 20460

NOTICE OF PESTICIDE
X Registration
___ Reregistration
(unde FIFRA as amended)

EPA Reg Number	Date of Issuan e
68467 6	OCT 2 7 2005

Term of Issuan | Cond tio l

Name of Pest c de Product
Herculex Xtra Insect Protection

Name and Address of Registrant (include ZIP Code)

Mycogen Seeds
c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis IN 46268

Note Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant the above named pesticide is hereby registered/reregistered under the Federal Insecticide Fungicide and Rodenticide Act

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency In order to protect health and the environment the Administrator on his motion may at any time suspend or cancel the registration of a pesticide in accordance with the Act The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others

This product is conditionally registered in accordance with FIFRA Sec 3(c)(7)(A) provided that you do the following terms and conditions

1) The subject registration will automatically expire on midnight October 15 2008

2) The subject registration will be limited to Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999) in Event TC1507 corn] X Cry34/35Ab1 [Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production (plasmid insert PHP17662) in Event DAS 59122 7 corn] corn for use in field corn

3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data

4) Submit all data required to support the individual plant incorporated protectants in Event TC1507 (Herculex I) and Event DAS 59122 7 (Herculex Rootworm) corn EPA Registration Nos 68467 2 and 68467 5 In the event that the Agency concludes Cry34/35Ab1 (Herculex Rootworm) studies do not sufficiently demonstrate a lack of long range adverse effects additional data with Herculex Xtra corn must be submitted This data may include a) laboratory toxicity testing with

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Orius insidiosus (minute pirate bug) b) laboratory toxicity testing with a carabid (ground beetle) c) long range effects testing on invertebrate populations in the field and d) long range soil persistence testing

5) You must do the following Insect Resistance Management Program

The required IRM program for Cry1FxCry34/35Ab1 corn has the following elements

1] Requirements relating to creation of a refuge for both the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits The refuge for both traits may be combined by planting non *Bt* corn as the refuge or the refuge for each trait may be planted separately In the latter case corn rootworm resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran resistant *Bt* corn may be planted in the corn rootworm refuge for the Cry34/35Ab1 component

2] Requirements for the registrants to prepare and require *Bt* corn users to sign grower agreements which impose binding contractual obligations on the grower to comply with the refuge requirements

3] Requirements for the registrants to develop implement and report to EPA on programs to educate growers about IRM requirements

4] Requirements for the registrants to develop implement and report to EPA on programs to evaluate and promote growers compliance with IRM requirements (the Cry1F x Cry34/35Ab1 Compliance Assurance Program (CAP) must integrate with the Cry1 and Cry34/35Ab1 CAPs)

5] Requirements for the registrants to develop implement and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1F and Cry34/35Ab1 proteins in the target insects

6] Requirements for the registrants to develop and if triggered to implement a remedial action plan which would contain measures the registrants would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA

7] Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request) IRM grower agreements results compliance assurance program including the education program on or before January 31st each year and for resistance monitoring on or before April 30th each year for Cry1F and on or before August 31st each for Cry34/35Ab1 beginning in 2007

5a Refuge Requirements

The use of Cry1F x Cry34/35Ab1 corn requires accompanying refuge corn for both the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits described below Therefuge for both traits may be combined by planting non *Bt* corn as the refuge (see C below) or the refuge for each trait may be planted separately (see A and B below)

For the separate refuges corn rootworm resistant *Bt* corn (e g Herculex RW) may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran resistant *Bt* corn (e g Herculex I) may be planted in the corn rootworm refuge for the Cry34/35Ab1 component Depending on cropping practices

pest problems and pest management options employed on any given farm growers may need to choose different refuge arrangements for different fields Possible options include two refuge blocks (one for rootworm one for Lepidoptera) can be planted within one field or strips can be used for either refuge Alternatively a block of Herculex RW corn can serve as an in field lepidopteran refuge for one field planted to Cry1F X Cry34/35Ab1 and an external lepidopteran refuge for separate fields planted to Cry1F X Cry34/35Ab1 while the rootworm refuge is planted as Herculex I corn in an external adjacent field In all options size and management of each individual refuge must be followed as described in A and B below

Other refuge designs and combinations are permissible as long as in all cases the size and management of each refuge are described in A B and C below

A Lepidopteran refuge for the Cry1F component

1 *Refuge size* Corn Growing Areas (= corn belt and other non corn/cotton growing regions) The use of Cry1F x Cry34/35Ab1 corn requires an accompanying 20% refuge consisting of non Bt corn or non lepidopteran resistant *Bt* corn

2 *Refuge size* (Corn/Cotton growing areas) * The use Cry1F x Cry34/35Ab1 corn requires an accompanying 50% refuge consisting of non Bt corn or non lepidopteran resistant *Bt* corn

3 *Refuge location*

The lepidopteran refuge can be planted in a separate field not more than ½ mile (1/4 mile preferred) of the Cry1F x Cry34/35Ab1 field

The lepidopteran refuge can be planted within the Cry1F x Cry34/35Ab1 field as blocks (e g along the edges or headlands)

The lepidopteran refuge can be planted within the Cry1F x Cry34/35Ab1 field as strips across the field at least four rows wide (six preferred)

4 *Refuge management*

Insecticide treatments for control of European corn borer corn earworm southwestern corn borer, fall armyworm black cutworm western bean cutworm lesser corn stalk borer sugarcane borer and southern corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests Economic thresholds will be determined using methods recommended by local or regional professionals (e g Extension Service Agents crop consultants) Microbial *Bt* insecticides must not be applied to lepidopteran resistant refuges

* Cotton growing areas consist of the following states Alabama Arkansas Georgia Florida Louisiana North Carolina Mississippi South Carolina Oklahoma (only the counties of Beckham, Caddo Comanche Custer Greer Harmon Jackson Kay Kiowa Tillman Washita) Tennessee (only the counties of Carroll Chester Crockett Dyer Fayette Franklin Gibson Hardeman Hardin Haywood Lake Lauderdale Lincoln Madison Obion Rutherford Shelby and Tipton) Texas (except the counties of Carson Dallam Hansford Hartley Hutchinson Lipscomb Moore Ochiltree Roberts and Sherman) Virginia (only the counties of Dinwiddie Franklin City Greensville Isle of Wight Northampton Southampton Suffolk City Surrey Sussex) and Missouri (only the counties of Dunkin New Madrid Pemiscot Scott Stoddard)

B Corn rootworm refuge for the Cry34/35Ab1 component

1 *Refuge size* The use of Cry1F x Cry34/35Ab1 corn requires an accompanying 20% refuge consisting of non Bt corn or non corn rootworm resistant *Bt* corn

2 *Refuge location* The rootworm refuge is required to be planted within or adjacent (e g across the road) to the Cry1F x Cry34/35Ab1 corn field

3 *Refuge management options* The rootworm refuge can be managed in such a way that there is little or no yield loss to rootworms but must be managed in a way that it is sufficiently productive of susceptible rootworm adults

The in field rootworm refuge options may be planted as a single block or as a series of strips measuring at least four (4) crop rows wide

Seed mixtures of Cry1F x Cry34/35Ab1 and rootworm refuge corn are not permitted

If the rootworm refuge is planted on rotated ground then Cry1F x Cry34/35Ab1 corn must also be planted on rotated ground

If the rootworm refuge is planted in continuous corn the Cry1F x Cry34/35Ab1 field may be planted on either continuous or rotated land (option encouraged where WCRW rotation resistant biotype may be present)

Application of soil insecticide is permitted in the rootworm refuge

Seed treatment is permitted in the rootworm refuge either at a rate for rootworm protection or at a rate for controlling secondary soil pests

If aerial insecticides are applied to the rootworm refuge for control of CRW adults the same treatment must also be applied in the same time frame to Cry1F x Cry34/35Ab1 corn

Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Cry1F x Cry34/35Ab1 acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used Pests on the Cry1F x Cry34/35Ab1 acres can be treated as needed without having to treat the rootworm refuge

The rootworm refuge can be planted to any corn hybrid that does not express PIPs for rootworm control (e g lepidopteran protected *Bt* corn herbicide tolerant corn or conventional corn)

The rootworm refuge and Cry1F x Cry34/35Ab1 corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties

Growers are encouraged to plant the rootworm refuge in the same location each year as it allows the rootworm population to remain high and the durability of the trait is extended This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn However for those growers who need to employ crop rotation a fixed refuge would be impractical

C For the combined refuge option (i e the lepidopteran refuge combined with the rootworm refuge by planting non Bt corn), the refuge must be planted and managed such that it is consistent with the requirements of the two individual traits as follows

1 *Refuge size* shall be 20% in corn growing areas and 50% in cotton growing areas (see list labeled with * under A)

2 *Refuge location* The combined refuge is required to be planted within or adjacent (e g across the road) to the Cry1F x Cry34/35Ab1 corn field

3 *Refuge management options*

- The in field refuge options must be planted as a single block or as a series of strips measuring at least four (4) rows wide (six rows preferred)
- Seed mixtures of Cry1F x Cry34/35Ab1 and refuge corn are not permitted
- If the combined refuge is planted on rotated ground then the Cry1F x Cry34/35Ab1 corn must also be planted on rotated ground
- If the combined refuge is planted on continuous corn the Cry1F x Cry34/35Ab1 field may be planted on either continuous or rotated land (option encouraged where WCRW rotation resistant biotype may be present)
- Application of soil insecticide for corn rootworm control is permitted in the combined refuge
- Seed treatment is permitted in the combined refuge either at a rate for rootworm protection or at a rate for controlling secondary soil pests
- If aerial insecticides are applied to the combined refuge for control of CRW adults the same treatment must also be applied in the same timeframe to Cry1F x Cry34/35Ab1 corn
- Insecticide treatments in the combined refuge for control of European corn borer corn earworm southwestern corn borer fall armyworm black cutworm western bean cutworm sugarcane borer lesser corn stalk borer or southern corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests Economic thresholds will be determined using methods recommended by local or regional professionals (e g Extension Service Agents crop consultants) These pests can be treated with CRW labeled insecticide on the combined refuge acres without treating the Cry1F x Cry34/35Ab1 acres only if treatment occurs when adults corn rootworms are not present Microbial *Bt* insecticides must not be applied to the common refuges
- Pests other than adult corn rootworms can be treated with CRW labeled insecticide on the combined refuge acres without treating the Cry1F x Cry34/35Ab1 acres only if treatment occurs when adults corn rootworms are not present Pests on the Cry1F x Cry34/35Ab1 acres can be treated as needed without having to treat the refuge
- The combined refuge can be planted to any corn hybrid that does not express PIPs for lepidopteran or rootworm control (i e herbicide tolerant corn or conventional corn)
- The combined refuge and Cry1F x Cry34/35Ab1 corn should be sown on the same day or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties

The description of the refuge requirements in the grower guide must be consistent with the preceding requirements

5b Grower Agreements

1] Persons purchasing the *Bt* corn product must sign a grower agreement The term grower agreement refers to any grower purchase contract license agreement or similar legal document

2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program By signing the grower agreement a grower must be contractually bound to comply with the requirements of the IRM program

3] The registrant must develop a system (equivalent to what is already approved for Cry1F Bt corn) which is reasonably likely to assure that persons purchasing the *Bt* corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program The proposed system will be submitted to EPA by January 31 2006

4] The registrant must use grower agreements and submit to EPA by January 31 2006 a copy of that agreement and any specific stewardship documents referenced in the grower agreement If Mycogen Seeds c/o Dow Agrosciences LLC wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program thirty days prior to implementing a proposed change the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment

5] The registrant must establish a system (equivalent to what is already approved for Cry1F Bt Corn) which is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s) and must provide by January 31 2006 a written description of that system

6] The registrant shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed

7] Beginning on January 31 2007 and annually thereafter the registrant shall provide EPA with a report showing the number of units of its Cry1F x Cry34/35Ab1 corn seeds sold or shipped and not returned and the number of such units that were sold to persons who have signed grower agreements The report shall cover the time frame of the twelve month period covering the prior August through July

8] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information including names personal information and grower license number will be protected

5c IRM Education and IRM Compliance Monitoring Programs

1] Mycogen Seeds c/o Dow Agrosciences LLC must implement a comprehensive ongoing IRM education program designed to convey to *Bt* Cry34/35Ab1 corn users the importance of complying with the IRM program The program shall include information encouraging *Bt* Cry1F x Cry34/35Ab1 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* Cry1F x Cry34/35Ab1 corn fields The education program shall involve the use of multiple media e g face-to face meetings mailing written materials EPA reviewed language on IRM requirements on the bag or bag tag and electronic communications such as by Internet radio or television commercials Copies of the materials will be provided to EPA for its records for the first year of commercialization (2006 growing season) by January 31 2007 The program shall involve at least one written communication annually to each *Bt* Cry1F x Cry34/35Ab1 corn user separate from the grower technical guide The communication shall inform the user of the current IRM requirements Mycogen Seeds c/o Dow Agrosciences LLC shall coordinate its education programs with educational efforts of other registrants and other organizations such as the National Corn Grower Association and state extension programs

2] Annually the registrant shall revise and expand as necessary its education program to take into account the information collected through the compliance survey required under paragraph 6] and from other sources The changes shall address aspects of grower compliance that are not sufficiently high

3] Beginning January 31 2008 and annually thereafter the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report The required features of the compliance assurance program are described in paragraphs 4] 15] below

4] The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its Cry1F x Cry34/35Ab1 *Bt* corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the Cry1F x Cry34/35Ab1 *Bt* corn product The registrant shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and integrate the Cry1F x Cry34/35Ab1 CAP with the Cry1 CAPs The registrant must prepare and submit by January 31 2006 a written description of their compliance assurance program including a summary of the program implemented in the 2006 growing season Other required features of the program are described in paragraphs 5] 15] below

5] The registrant must establish and publicize a phased compliance approach i e a guidance document that indicates how the registrant will address instances of non compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non compliant growers The options shall include withdrawal of the right to purchase Cry1F x Cry34/35Ab1*Bt* corn for an individual grower or for all growers in a specific region An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year Similarly seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Cry1F x Cry34/35Ab1*Bt* corn

6] The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of Cry1F x Cry34/35Ab1*Bt* corn growers who plant the vast majority of all corn in the U S and in areas in which the selection intensity is greatest The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn cotton areas The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non response The sample size and geographical resolution may be adjusted annually based upon input from the independent marketing research firm and academic scientists to allow analysis of compliance behavior within regions or between regions The sample size must provide a reasonable sensitivity for comparing results across the U S

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements An analysis of the survey results must include the reasons extent and potential biological significance of any implementation deviations

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives

9] The registrant shall provide a written summary of the results of the prior year s survey (together with a description of the regions the methodology used and the supporting data) to EPA by January 31 of each year beginning with 2007 The registrant shall confer with EPA on the design and content of the survey prior to its implementation

10] Annually the registrant shall revise and expand as necessary its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6] through 8] and from other sources The changes shall address aspects of grower compliance that are not sufficiently high The registrant must confer with the Agency prior to adopting any significant changes

11] The registrant shall conduct an annual on farm assessment program The registrant shall train its representatives who make on farm visits with Cry1F x Cry34/35Ab1*Bt* corn growers to perform

assessments of compliance with IRM requirements There is no minimum corn acreage size for this program Therefore growers will be selected for this program from across all farm sizes In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program the registrant shall take appropriate action consistent with its phased compliance approach to promote compliance

12] The registrant shall carry out a program for investigating legitimate tips and complaints that its growers are not in compliance with the IRM program Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program the registrant shall take appropriate action consistent with its phased compliance approach

13] If a grower who purchases Cry1F x Cry34/35Ab1*Bt* corn for planting was specifically identified as not being in compliance during the previous year the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year

14] Beginning January 31 2007 and annually thereafter Mycogen Seeds c/o Dow Agrosciences LLC shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year including changes to the grower education program and the plans for the compliance assurance program during the current year The report will include information regarding grower interactions (including but not limited to third party grower survey on farm visitation program verified tips and complaints education programs (e g grower meetings and letters) the extent of non compliance corrective measures to address the non compliance (phased compliance program) and any follow up actions taken

15] The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information including the names personal information and grower license number of the growers will be protected

5d Insect Resistance Monitoring

The Agency is imposing the following conditions for this product

A report on results of Cry1F resistance monitoring and investigations of damage reports must be submitted to the Agency annually by April 31**st** each year for the duration of the conditional registration You must provide EPA with an annual Cry34/35Ab1 resistance monitoring report by August 31st of each year beginning with 2008 reporting on populations collected the previous year

Cry1 F

1) Dow will monitor for resistance and/or trends in increased tolerance for *Ostrinia nubilalis (*European corn borer) *Diatraea grandiosella (*Southwestern corn borer) and/or *Helicoverpa zea* (corn earworm) Sampling should be focused in those areas in which there is the highest risk of resistance development The ABSTC has identified four regions for its compliance and monitoring programs

2) The registrant shall provide to EPA a description of its Cry1F resistance monitoring plan by January 31 2006 The description shall include sampling (number of locations and samples per locations) sampling methodology bioassay methodology standardization procedures detection technique and

sensitivity and the statistical analysis of the probability of detecting resistance

3) The registrant must follow up on grower extension specialist or consultant reports of less than expected results or control failures for the target lepidopteran pests *Ostrinia nubilalis* (ECB) *Diatraea grandiosella* (SWCB) *Helicoverpa zea* (CEW/CBW) *Spodoptera frugiperda* (FAW) *Agrotis ipsilon* (BCW) and *Richia albicosta* (WBCW)
Sugar cane borer *Diatraea saccharalis* southern corn stalk borer *Diatraea crambidoides* lesser corn stalk borer *Elasmopalpus lignosellus* The registrant will instruct its customers (growers and seed distributors) to contact them (e g via a toll free customer service number) if incidents of unexpected levels of damage occurs from these target pests The registrant will investigate all damage reports submitted to the company or the companys representatives See Remedial Action Plans section below

Cry34/35Ab1

The registrant must monitor for Cry34Ab1/35Ab1 resistance and/or trends in increased tolerance for corn rootworm Sampling should be focused in those areas in which there is the highest risk of resistance development

1) The registrant must provide EPA its resistance monitoring plan for approval A preliminary plan must be submitted to the Agency by January 31 2006 consisting of a description of the steps to be taken to establish corn rootworm baseline sensitivity and damage guidelines A detailed resistance monitoring plan must be submitted to the Agency for review by January 31 2008 This plan must include baseline sensitivity data sampling (number of locations samples per locations) sampling methodology and life stage sampled bioassay methodology standardization procedures (including QA/QC provisions) detection technique and sensitivity the statistical analysis of the probability of detecting resistance and an interim description of rootworm damage guidelines

2) The registrant must develop and validate an appropriate discriminating or diagnostic dose assay by January 31 2010 Further you must provide BPPD with a detailed explanation and validation (steps for) of the high throughput diagnostic screen if it is to be considered an acceptable diagnostic dose assay

3) You must finalize rootworm damage guidelines and submit these to BPPD by January 31 2010 should the registration be extended

4) The registrant must follow up on grower extension specialist or consultant reports of unexpected damage or control failures for corn rootworm

5e Remedial Action Plans

Cry1F

A Remedial Action Plan covering both suspected and confirmed resistance for European corn borer corn earworm and southwestern corn borer follows If resistance involves any of these three target pests the registrant must implement this Remedial Action Plan The registrant must obtain approval from EPA before modifying the Remedial Action Plan for Lepidopteran Protected Corn

I Definitions

Suspected resistance

EPA defines suspected resistance to mean in the case of reported product failure that the corn in question has been confirmed to be *Bt* corn

> the seed used had the proper percentage of corn expressing *Bt* protein
> the relevant plant tissues are expressing the expected level of *Bt* protein and
> it has been ruled out that species not susceptible to the protein could be responsible for the damage that no climatic or cultural reasons could be responsible for the damage and that other reasonable causes for the observed product failure have been ruled out The Agency does not interpret suspected resistance to mean grower reports of possible control failures nor does the Agency intend that extensive field studies and testing to confirm scientifically insect resistance be completed before responsive measures are undertaken

If resistance is suspected the registrant must instruct growers to do the following

> Use alternate control measures to control the pest suspected of resistance to *Bt* corn in the affected region
> Destroy crop residues in the affected region immediately after harvest (i e within one month) with a technique appropriate for local production practices to minimize the possibility of resistant insects overwintering and contributing to the next season s pest population

Confirmed Resistance

The registrant assumes responsibility for the implementation of resistance mitigation actions undertaken in response to the occurrence of resistance during the growing season When resistance has been confirmed the registrant must immediately stop sale and distribution of *Bt* corn in the remedial action zone (may be less than a single county single county or multiple counties) where the resistance has been shown until an effective local mitigation plan approved by EPA has been implemented

A resistance event becomes confirmed if the progeny of the sampled ECB CEW or SWCB population would exhibit all of the following characteristics in bioassays initiated with neonates

1 If there is > 30% survival and > 25% leaf area damaged in a 5 day bioassay using Cry1Ab positive or Cry1F positive leaf tissue under controlled laboratory conditions

2 If standardized laboratory bioassays using diagnostic doses for ECB (Marçon et al 2000) SWCB (Trisyono and Chippendale 1999) or CEW/CBW (USDA/ARS/SIMRU unpublished) demonstrate resistance has a genetic basis and survivorship in excess of 1% (gene frequency of population ?0 1)

3 If an LC50 in a standard Cry1Ab or Cry1F diet bioassay exceeds the upper limit of the 95% confidence interval of the standard unselected laboratory population LC50 for susceptible ECB SWCB or CEW populations as established by the ongoing baseline monitoring program

II Remedial Action

The registrant assumes responsibility for the implementation of resistance mitigation actions undertaken in response to the occurrence of resistance during the growing season In cases of confirmed resistance the following strategy for Cry1Ab and/or Cry1F *Bt* corn hybrids

The registrant will report all instances of confirmed pest resistance as defined above to the Agency within 30 days Upon identification of a confirmed instance of resistance registrants will take the following immediate mitigation measures

1 Notify customers and extension agents in the affected area

2 Require to customers and extension agents in the affected area the use of alternative control measures to reduce or control the local target pest population

3 Where appropriate require to customers and extension agents in the affected area that crop residues be incorporated into the soil following harvest to minimize the possibility of overwintering insects

4 Immediately stop sale and distribution of *Bt* corn in the remedial action zone (may be a single or multiple counties) where the resistance has been shown until an effective local mitigation plan approved by EPA has been implemented

Within 90 days of a confirmed instance of pest resistance as defined above registrants will

1 Notify the Agency of the immediate mitigation measures that were implemented

2 Submit to the Agency a proposed long term resistance management action plan for the affected area

3 Work closely with the Agency in assuring that an appropriate long term resistance management action plan for the affected area is implemented and

4 Implement an action plan that is approved by EPA and that consists of some or all the following elements as warranted

a Informing customers and extension agents in the affected area of pest resistance

b Increasing monitoring in the affected area, and ensuring that local target pest populations are sampled on an annual basis

c Recommending alternative measures to reduce or control target pest populations in the affected area

d Implementing intensified local IRM measures in the affected area based on the latest research results The implementation of such measures will be coordinated by the Agency with other registrants and

e The implementation of the remedial action strategy will be coordinated by the Agency with other registrants and stakeholders

For mitigation of resistance in the growing season(s) following a confirmed resistance incident(s) use of the following procedures

1 Maintenance of the sales suspension of all *Bt* corn hybrids (with the same protein or similar *Bt* proteins as the *Bt* corn hybrids with the resistant population) in the affected region would remain in place until an EPA approved local resistance management plan is in place to mitigate resistance in the affected region(s)

2 The development and recommendation of alternative resistance management strategies for controlling the resistant pest(s) on corn in the affected region

3 Notification of all relevant personnel (e g growers consultants extension agents seed distributors processors university cooperators and state/federal authorities) in the affected region of the resistance situation

Cry34/35Ab1

The remedial action plan is designed as a tiered approach for mitigating WCRW NCRW and MCRW resistance development to the Cry34/35Ab1 protein The following program summary describes in order of events the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed However the levels of expected damage cannot be identified until baseline sensitivity is determined EPA requires that Dow AgroSciences/Mycogen Seeds LLC establish the baseline sensitivity by January 31 2008 so that expected levels of crop damage and target pest resistance can be established and a remedial action plan initiated when needed

1] **Definition of Suspected Resistance** Resistance will be suspected if investigations of unexpected damage reports show that

a implicated corn plant roots were expressing Cry34/35Ab1 proteins at the expected levels
b the seed used was not mixed with non Cry34/35Ab1 seed
c alternative causes of damage or lodging such as non target pest insect species, weather physical damage larval movement from alternate hosts planting errors and other reasonable causes for the observations have been ruled out
d the level of damage exceeds guidelines for expected damage

If resistance is suspected the registrant will instruct affected growers to use alternate pest control measures such as adulticide treatment crop rotation the following year or use of soil or seed insecticides the following year These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year s pest population

2] **Confirmation of Resistance** Resistance will be confirmed if all of the following criteria are met by progeny from the target pest species sampled from the area of suspected resistance

a the proportion of larvae that can feed and survive on Cry34/35Ab1 roots from neonate to adult is significantly higher than the baseline proportion (currently being established)
b the LC50 of the test population exceeds the upper limit of the 95% confidence interval for the LC50 of a standard unselected population and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population as established by the ongoing baseline monitoring program
c the ability to survive is heritable

d Cry34/35Ab1 plant assays determine that damage caused by surviving insects would exceed economic thresholds
e if subsequent collections in the affected field area demonstrate similar bioassay results

3] **Response to Confirmed Resistance** When resistance is confirmed the following steps will be taken

a EPA will receive notification within 30 days of confirming resistance
b affected customers and extension agents will be notified about confirmed resistance
c affected customers and extension agents will be encouraged to employ alternative CRW control measures
d sale and distribution of Cry34/35Ab1 corn in the affected area will cease immediately
e a long term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs

If these conditions are not complied with the registration will be subject to cancellation in accordance with FIFRA sec 6(e)

A stamped copy of the label is enclosed for your records

Sincerely

Dennis Szuhay Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511C)

Herculex™ XTRA
Insect Protection

Active Ingredient	
Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999 event TC1507) in corn	0 000288 – 0 001740%
Bacillus thuringiensis Cry34Ab1 insecticidal crystal protein and the genetic material necessary for its production (plasmid insert PHP17662 event DAS 59122 7) in corn	0 006480 – 0 016840 %
Bacillus thuringiensis Cry35Ab1 insecticidal crystal protein and the genetic material necessary for its production (plasmid insert PHP17662 event DAS 59122 7) in corn	0 001950 – 0 006760 /
Inert Ingredient	
Substance produced by a marker gene and its controlling sequences in corn	0 000003 – 0 001510 %

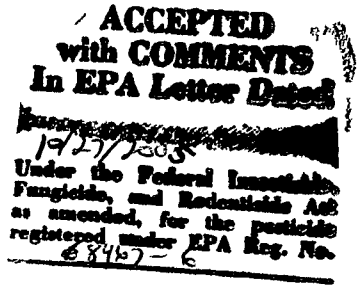
% total protein on a dry wt basis as expressed in corn plant cells (whole plant)

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Reg No 68467 6 EPA Est 029964 IA 001

Mycogen Seeds
c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis IN 46268

™Trademark of Dow AgroSciences LLC



DIRECTIONS FOR USE

It is a violation of federal law to use this product in any manner inconsistent with its labeling

The subject registration automatically expires at midnight on midnight October 15 2008

The plant incorporated protectant product must be used as specified in the terms and conditions of the registration

Herculex XTRA combines the insect protection features of Herculex I and Herculex RW in the same corn hybrid (inbred) Herculex XTRA hybrids protect corn crops from leaf stalk and ear damage caused by Lepidopteran corn pests such as the European corn borer and root damage caused by corn rootworm larvae In order to minimize the risk of the corn pests developing resistance to Herculex XTRA corn an insect resistance management plan must be implemented

Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the Product Use Guide for Herculex XTRA corn or other applicable product use documents

Growers are instructed to read information on insect resistance management The following information regarding refuge placement for commercial production must be included in the Growing Guide

The use of Cry1F x Cry34/35Ab1 corn requires accompanying refuge corn for both the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits described below The refuge for both traits may be combined by planting non *Bt* corn as the refuge (see C below) or the refuge for each trait may be planted separately (see A and B below)

For the separate refuges corn rootworm resistant *Bt* corn (e g Herculex RW) may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran resistant *Bt* corn (e g Herculex I) may be planted in the corn rootworm refuge for the Cry34/35Ab1 component Depending on cropping practices pest problems and pest management options employed on any given farm growers may need to choose different refuge arrangements for different fields Possible options include two refuge blocks (one for rootworm one for Lepidoptera) can be planted within one field or strips can be used for either refuge Alternatively a block of Herculex RW corn can serve as an in field lepidopteran refuge for one field planted to Cry1F X Cry34/35Ab1 and an external lepidopteran refuge for separate fields planted to Cry 1F X Cry34/35Ab1 while the rootworm refuge is planted as Herculex I corn in an external adjacent field In all options size and management of each individual refuge must be followed as described in A and B below

Other refuge designs and combinations are permissible as long as in all cases the size and management of each refuge are described in A B and C below

A Lepidopteran refuge for the Cry1F component

1 *Refuge size* Corn Growing Areas (= corn belt and other non corn/cotton growing regions) The use of Cry1F x Cry34/35Ab1 corn requires an accompanying 20% refuge consisting of non Bt corn or non lepidopteran resistant *Bt* corn

2 *Refuge size* (Corn/Cotton growing areas) The use Cry1F x Cry34/35Ab1 corn requires an accompanying 50% refuge consisting of non *Bt* corn or non lepidopteran resistant *Bt* corn

3 *Refuge location*

The lepidopteran refuge can be planted in a separate field not more than / mile (1/4 mile preferred) of the Cry1F x Cry34/35Ab1 field

- The lepidopteran refuge can be planted within the Cry1F x Cry34/35Ab1 field as blocks (e g along the edges or headlands)

- The lepidopteran refuge can be planted within the Cry1F x Cry34/35Ab1 field as strips across the field at least four rows wide (six preferred)

4 *Refuge management*

- Insecticide treatments for control of European corn borer corn earworm southwestern corn borer fall armyworm black cutworm western bean cutworm lesser corn stalk borer sugarcane borer and southern corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests Economic thresholds will be determined using methods recommended by local or regional professionals (e g Extension Service Agents crop consultants) Microbial *Bt* insecticides must not be applied to lepidopteran resistant refuges

Cotton growing areas consist of the following states Alabama Arkansas Georgia Florida Louisiana North Carolina Mississippi South Carolina Oklahoma (only the counties of Beckham Caddo Comanche Custer Greer Harmon Jackson Kay Kiowa Tillman Washita) Tennessee (only the counties of Carroll Chester Crockett Dyer Fayette Franklin Gibson Hardeman Hardin Haywood Lake Lauderdale Lincoln Madison Obion Rutherford Shelby and Tipton) Texas (except the counties of Carson Dallam Hansford Hartley Hutchinson Lipscomb Moore Ochiltree Roberts and Sherman) Virginia (only the counties of Dinwiddie Franklin City Greensville Isle of Wight Northampton Southampton Suffolk City Surrey Sussex) and Missouri (only the counties of Dunkin New Madrid Pemiscot Scott Stoddard)

B Corn rootworm refuge for the Cry34/35Ab1 component

1 *Refuge size* The use of Cry1F x Cry34/35Ab1 corn requires an accompanying 20 % refuge consisting of non Bt corn or non corn rootworm resistant *Bt* corn

2 *Refuge location* The rootworm refuge is required to be planted within or adjacent (e g across the road) to the Cry1F x Cry34/35Ab1 corn field

3 *Refuge management options* The rootworm refuge can be managed in such a way that there is little or no yield loss to rootworms but must be managed in a way that it is sufficiently productive of susceptible rootworm adults

The in field rootworm refuge options may be planted as a single block or as a series of strips measuring at least four (4) crop rows wide

Seed mixtures of Cry1F x Cry34/35Ab1 and rootworm refuge corn are not permitted

- If the rootworm refuge is planted on rotated ground then Cry1F x Cry34/35Ab1 corn must also be planted on rotated ground
- If the rootworm refuge is planted in continuous corn the Cry1F x Cry34/35Ab1 field may be planted on either continuous or rotated land (option encouraged where WCRW rotation resistant biotype may be present)

  Application of soil insecticide is permitted in the rootworm refuge

  Seed treatment is permitted in the rootworm refuge either at a rate for rootworm protection or at a rate for controlling secondary soil pests
- If aerial insecticides are applied to the rootworm refuge for control of CRW adults the same treatment must also be applied in the same time frame to Cry1F x Cry34/35Ab1 corn

  Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Cry1F x Cry34/35Ab1 acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used Pests on the Cry1F x Cry34/35Ab1 acres can be treated as needed without having to treat the rootworm refuge

  The rootworm refuge can be planted to any corn hybrid that does not express PIPs for rootworm control (e g lepidopteran protected *Bt* corn herbicide tolerant corn or conventional corn)

The rootworm refuge and Cry1F x Cry34/35Ab1 corn should be sown on the same day or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties

- Growers are encouraged to plant the rootworm refuge in the same location each year as it allows the rootworm population to remain high and the durability of the trait is extended This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn However for those growers who need to employ crop rotation a fixed refuge would be impractical

C For the combined refuge option (i e the lepidopteran refuge combined with the rootworm refuge by planting non Bt corn) the refuge must be planted and managed such that it is consistent with the requirements of the two individual traits as follows

1 *Refuge size* shall be 20% in corn growing areas and 50 % in cotton growing areas (see list labeled with under A)

2 *Refuge location* The combined refuge is required to be planted within or adjacent (e g across the road) to the Cry1F x Cry34/35Ab1 corn field

3 *Refuge management options*

The in field refuge options must be planted as a single block or as a series of strips measuring at least four (4) rows wide (six rows preferred)
Seed mixtures of Cry1F x Cry34/35Ab1 and refuge corn are not permitted
If the combined refuge is planted on rotated ground then the Cry1F x Cry34/35Ab1 corn must also be planted on rotated ground
If the combined refuge is planted on continuous corn the Cry1F x Cry34/35Ab1 field may be planted on either continuous or rotated land (option encouraged where WCRW rotation resistant biotype may be present)

- Application of soil insecticide for corn rootworm control is permitted in the combined refuge Seed treatment is permitted in the combined refuge either at a rate for rootworm protection or at a rate for controlling secondary soil pests
  If aerial insecticides are applied to the combined refuge for control of CRW adults the same treatment must also be applied in the same timeframe to Cry1F x Cry34/35Ab1 corn
  Insecticide treatments in the combined refuge for control of European corn borer corn earworm southwestern corn borer fall armyworm black cutworm western bean cutworm sugarcane borer lesser corn stalk borer or southern corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests Economic thresholds will be determined using methods recommended by local or regional professionals (e g Extension Service Agents crop consultants) These pests can be treated with CRW labeled insecticide on the combined refuge acres without treating the Cry1F x Cry34/35Ab1 acres only if treatment occurs when adults corn rootworms are not present Microbial *Bt* insecticides must not be applied to the common refuges
  Pests other than adult corn rootworms can be treated with CRW labeled insecticide on the combined refuge acres without treating the Cry1F x Cry34/35Ab1 acres only if treatment occurs when adults corn rootworms are not present Pests on the Cry1F x Cry34/35Ab1 acres can be treated as needed without having to treat the refuge
- The combined refuge can be planted to any corn hybrid that does not express PIPs for lepidopteran or rootworm control (i e herbicide tolerant corn or conventional corn)
- The combined refuge and Cry1F x Cry34/35Ab1 corn should be sown on the same day or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties

Use Pattern

Crop	Pests
Field corn	black cutworm corn earworm European corn borer fall armyworm Mexican corn rootworm northern corn rootworm southwestern corn borer western bean cutworm western corn rootworm lesser corn stalk borer southern corn stalk borer sugarcane borer

EPA Accepted __/__/__